REMARKS

By this Amendment, the specification and claims 1 and 13 have been amended and claims 12 and 22 have been canceled. No new claims have been added to the application. Accordingly, claims 1, 4-11 and 13-21 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner rejected claims 1 and 4-22 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the following three limitations set forth in the claims constitute new matter:

(1) the polymer, wax and/or lipid is contacted with the supercritical fluid in the absence of any solvents to form a melt;

(2) the collection vessel is maintained above the boiling point of the solvent; and

(3) the solvent is volatized.

Applicants respectfully submit that there is adequate support in the specification for each of the claim limitations set forth above.

With respect to limitation (1), Figs. 1 and 2 and paragraph [0032] describe that the supercritical fluid contacts the polymer, lipid and/or wax optionally in the presence of one or more co-solvents. It only stands to reason that if the one or more co-solvents are optional, the specification is enabled for circumstances when the supercritical fluid contacts the polymer when no solvents are present (i.e., in the absence of any solvents). Applicants have amended paragraph [0032] of the specification to expressly state that which is claimed, and which is clearly enabled.

With respect to limitation (2), applicants note that original claim 3 (which was canceled by Preliminary Amendment) expressly claimed that the collection vessel was maintained above the boiling point of the solvent. Inasmuch as the claims are part of

the specification, this limitation is clearly enabled. Applicants have amended paragraph [0035] of the specification to expressly state that which is claimed, and is clearly enabled.

And, with respect to limitation (3), the specification clearly indicates that the solvent present during expansion is removed from the chamber via evaporation. Evaporation is a process whereby a liquid phase material is volatized. However, in an attempt to further clarify the invention, applicants have amended claims 1 and 13 to specify that the solvent is evaporated as opposed to volatized. Applicants have also amended claims 1 and 13 to clarify that the supercritical fluid is flashed into a gas, as is disclosed in the specification. Applicants thus respectfully request reconsideration of the rejection of claims 1, 4-11 and 13-21 under 35 U.S.C. §112, first paragraph.

Also in the prior Office Action, the Examiner rejected claims 1, 4 and 13-21 on nonstatutory obviousness-type double patenting grounds as being unpatentable over claims 1-10 of Shekunov et al., U.S. Pat. 6,986,846, in view of Sievers et al., U.S. Pat. 5,639,441 (hereinafter "Sievers '441"). To overcome this rejection, applicants have contemporaneously submitted a terminal disclaimer with this Amendment.

The Examiner rejected claims 12 and 22 under 35 U.S.C. §102(b) in the prior Office Action as being anticipated by, or in the alternative, under 35 U.S.C. §103(a), as obvious over Patel et al., U.S. Pat. 6,248,363 or Sievers et al, U.S. Pat. 6,630,121 (hereinafter "Sievers '121"). By this amendment, claims 12 and 22 have been canceled, thereby rendering the prior rejection thereof moot.

In the prior Office Action, the Examiner rejected claims 1, 4-11 and 13-21 under 35 U.S.C. §103(a) as being unpatentable over Patel et al. in view of Sievers '441 and Sievers '121. On page 6 of the prior Office Action, the Examiner states that Patel et al. discloses:

> producing composite particles from pharmaceutical feed mixtures comprising particles that are formed into melts, method steps employing supercritical fluid, solvents, solutes, formation of masses, and expansion/evaporation/volatization/ steps to form the composite particles.

Applicants agree that Patel et al. describes many different processes for producing composite particles from pharmaceutical feed mixtures. Applicants further agree that some of the processes disclosed in Patel et al. involve melting the components. Some of the processes involve the use of supercritical fluids. Some of the processes involve the use of solvents. Some of the processes involve the use of solutes. And some of the processes involve the formation of masses and expansion/evaporation/volatization. But applicants note that with respect to supercritical fluid processing, Patel teaches only the following (see col. 48, lines 55-61):

> Supercritical fluid Processes
>
> Components of the present invention can be dispersed in a supercritical fluid and crystallized as needed. Current techniques involving supercritical fluids include precipitation by rapid expansion of supercritical solutions, gas anti-solvent processes, and precipitation from gas saturated solutions.

There is nothing in Patel et al. that teaches or suggests applicants' method of producing particles as claimed in claims 1 and 13. For example, there is nothing in Patel et al. that teaches contacting a polymer, a wax and/or a lipid that is a solid at standard temperature and pressure with a supercritical fluid in the absence of any solvents to form a melt as claimed in claims 1 and 13. There is nothing in Patel et al. that teaches contacting the melt with a solution comprising a solute dissolved in a solvent that is at least partially soluble in the supercritical fluid to form a mass comprising: a melt-rich fraction comprising the melt, a first portion of the supercritical fluid, and the solute, wherein the solute is in the form of solid particles that are dispersed in the melt; and a supercritical fluid-rich fraction comprising a second portion of the supercritical fluid and the solvent as claimed in claims 1 and 13. There is nothing in Patel et al. that teaches expanding the mass across a pressure drop into a collection vessel maintained above the boiling point of the solvent to evaporate the solvent and flash the supercritical fluid into a gas and thus form composite particles comprising the polymer, wax and/or lipid and the solute as claimed in claim 1. And, there is nothing in Patel et al. that teaches extracting the solvent from the supercritical fluid-rich fraction to

form a solvent-free residual mass and expanding the solvent-free residual mass across a pressure drop into a collection vessel to flash the supercritical fluid into a gas and thus form solid particles comprising the polymer, wax and/or lipid and the solute as claimed in claim 13. Patel et al. merely mentions some of the ingredients or components that are used in applicants' claimed methods. But Patel et al. does not teach the same method steps as claimed by applicants.

The Examiner appears to recognize that Patel et al. does not disclose, teach or suggest applicants' claimed methods. On page 6 of the prior Office Action, the Examiner states that:

> The claims all differ in requiring mixing of the other melt ingredients with first supercritical fluid followed by addition of a solvent that is at least partially miscible/soluble with the supercritical fluid. The claims also require that the contacting with fluid and solvent and the expansion/volatization etc. be in separate vessels in series, and that the solvent and supercritical fluid be vaporized out, etc. However, Sievers '441 produces pharmaceutical particles by steps of sequentially mixing the ingredients with supercritical fluid and then with a miscible solvent, followed by expansion/pressure drop, etc. in separate chambers of vessels (see especially column 10, lines 27-52). Sievers '121 employs the Sievers '441 process steps (incorporates by reference, see column 1, line 65-column 2, line 14) and applies them to form particles comprised of melts, supercritical fluid and solvent (column 14, lines 18-33). It would have been obvious to employed the process steps of Sievers et al. '441/Sievers et al. '121 in the Patel et al process, to facilitate production of particles of better-controlled and more uniform particle size ranges and to facilitate industrial scale-up of the particle production process.

Applicants respectfully submit that Sievers '441 and Sievers '121 do not fairly teach or suggest applicants' claimed methods. Sievers '441 does not mention "melts" at all. And Sievers '121 mentions "melts" only one time as follows:

> The multichannel restrictor may be used to form particles of various substances, including fluids; melts; solutions; supercritical fluids and solutions or suspensions of supercritical fluids and aqueous and/or organic solvents; emulsions; microemulsions; micelles; reverse micelles and other substances into aerosols containing fine particles of solids (amorphous or crystalline).

A multichannel restrictor is shown in Figs. 3 and 4, and described on col. 13, lines 18-44 of Sievers '121.

Clearly, neither Patel et al., Sievers '441 nor Sievers '121 fairly teach "contacting a polymer, a wax and/or a lipid that is a solid at standard temperature and pressure with a supercritical fluid in the absence of any solvents to form a melt" as claimed in claims 1 and 13. And the mere statement in Sievers '121 that a multichannel restrictor may be used to form particles of "melts" does not suffice to overcome this deficiency.

Claims 1 and 13 of the present invention further claim, in pertinent part:

> contacting the melt with a solution comprising a solute dissolved in a solvent that is at least partially soluble in the supercritical fluid to form a mass comprising:
> a melt-rich fraction comprising the melt, a first portion of the supercritical fluid, and the solute, wherein the solute is in the form of solid particles that are dispersed in the melt; and
> a supercritical fluid-rich fraction comprising a second portion of the supercritical fluid and the solvent;

Again, neither Patel et al., Sievers '441 nor Sievers '121 fairly teach this. Patel et al. and Sievers '441 do not disclose any supercritical fluid processes that involve forming a melt. And Sievers '121 only mentions "melts" in the context of the multichannel restrictor. One simply cannot arrive at applicants' claimed method based on the information provided in Patel et al., Sievers '441 and/or Sievers '121.

Claim 13 of the present application further claims "extracting the solvent from the supercritical fluid-rich fraction to form a solvent-free residual mass; and expanding the solvent-free residual mass across a pressure drop into a collection vessel to flash the supercritical fluid into a gas and thus form solid particles comprising the polymer, wax and/or lipid and the solute." (underlined emphasis added). Again, neither Patel et al., Sievers '441 nor Sievers '121 fairly teach this.

The determination regarding whether an invention as claimed is obvious in view of the prior art must be made in accordance with the standards set forth in the Supreme Court's opinion in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ , 82 U.S.P.Q.2d 1385 (2007). In the *KSR* case, the Court made it clear that in order to reject a claim under 35 U.S.C. §103, there must be an explicit analysis explaining the apparent reason

why a person of ordinary skill in the art would combine known elements described in the prior art in the way claimed. The person of ordinary skill in the art would have to see the benefit of making the combination. The person of ordinary skill in the art would have to recognize that it would improve similar devices or methods in the same way. The critical inquiry is whether the claimed improvement is more than the predictable use of prior-art elements according to their established functions. If it is, then the improvement is not obvious under 35 U.S.C. §103(a). In the present case, the analysis required by *KSR* requires a finding that applicants' invention, as claimed, is not obvious in view of Patel et al. in view of Sievers '441 and/or Sievers '121. The applied references do not teach methods of producing particles that employ the same steps as claimed in the present application. Applicants' methods, as claimed, do not involve the use of known process steps in accordance with their established functions to obtain a predictable result.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 18-0160, Order No. FER-14650.001.001.

Respectfully submitted,

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